

§ 158.2173

40 CFR Ch. I (7–1–13 Edition)

TABLE—EUP MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance Data to Support MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods- animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes.* The following test note is applicable to the data requirements for experimental use permit microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:

i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and

ii. The use pattern is such that residues may be present in or on food or feed crops.

**§ 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.**

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular microbial pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not re-

quired; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticide toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
885.3050	Acute oral toxicity/pathogenicity	R	TGAI	1
885.3150	Acute pulmonary toxicity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/pathogenicity/ (intravenous) Acute injection toxicity/pathogenicity/ (intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity incidents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP, EP	1, 5
870.1200	Acute dermal toxicity	R	MP, EP	5
870.1300	Acute inhalation toxicity	R	MP, EP	5, 6
870.2400	Acute eye irritation	R	MP, EP	5
870.2500	Primary dermal irritation	CR	MP, EP	5

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.

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2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed type reactions of humans or domestic animals occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use that would result in an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

**§ 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.**

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data require-

ments for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

**TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS**

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
				Food/Feed/Nonfood	Forestry	Residential	Greenhouse	Indoor	Industrial		
						Outdoor					
Food/Feed	Nonfood										
885.4050	Avian oral toxicity	NR	R	R	R	R	NR	NR	NR	TGAI	1, 2
885.4200	Freshwater fish toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4240	Freshwater invertebrate toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4300	Nontarget plant testing	NR	NR	NR	R	NR	NR	NR	NR	TEP	1, 4
885.4340	Nontarget insect testing	R	R	R	R	NR	NR	NR	NR	TGAI	1, 5
885.4380	Honey bee testing	R	R	R	R	NR	NR	NR	NR	TGAI	1